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Amendments to specification

Beginning on P. 14, Line 3 DT

~~[0073]~~ Referring now to FIG. 6, a still further embodiment of a cartridge according to the present invention will be described. FIG. 6 shows one embodiment of a cartridge 300 which may be removably inserted into an apparatus for driving penetrating members to pierce skin or tissue. The cartridge 300 has a plurality of penetrating members 302 that may be individually or otherwise selectively actuated so that the penetrating members 302 may extend outward from the cartridge, as indicated by arrow 304, to penetrate tissue. In the present embodiment, the cartridge 300 may be based on a flat disc with a number of penetrating members such as, but in no way limited to, (25, 50, 75, 100, . . .) arranged radially on the disc or cartridge ~~800~~ 300. It should be understood that although the cartridge 300 is shown as a disc or a disc-shaped housing, other shapes or configurations of the cartridge may also work without departing from the spirit of the present invention of placing a plurality of penetrating members to be engaged, singly or in some combination, by a penetrating member driver.

Beginning on P. 14, Line 16 DT

~~[0074]~~ Each penetrating member 302 may be contained in a cavity 306 in the cartridge 300 with the penetrating member's sharpened end facing radially outward and may be in the same plane as that of the cartridge. The cavity 306 may be molded, pressed, forged, or otherwise formed in the cartridge. Although not limited in this manner, the ends of the cavities 306 may be divided into individual fingers (such as one for each cavity) on the outer periphery of the disc. The particular shape of each cavity 306 may be designed to suit the size or shape of the penetrating member therein or the amount of space desired for placement of the analyte detecting members ~~808~~ 308. For example and not limitation, the cavity 306 may have a V-shaped cross-section, a U-shaped cross-section, C-shaped cross-section, a multi-level cross section or the other cross-sections. The opening ~~810~~ 310 through which a penetrating member 302 may exit to penetrate tissue may also have a variety of shapes, such as but not limited to, a circular opening, a square or rectangular opening, a U-shaped opening, a narrow opening that

only allows the penetrating member to pass, an opening with more clearance on the sides, a slit, a configuration as shown in FIG. 75, or the other shapes.

Beginning on P. 15, line 31 (PT)

~~[0078]~~ In a still further feature of FIG. 6, the cartridge 300 may optionally include a plurality of analyte detecting members 308 on a substrate ~~822~~ 322 which may be attached to a bottom surface of the cartridge 300. The substrate may be made of a material such as, but not limited to, a polymer, a foil, or other material suitable for attaching to a cartridge and holding the analyte detecting members 308. As seen in FIG. 6, the substrate 322 may hold a plurality of analyte detecting members, such as but not limit,ed to, about 10-50, 50-100, or other combinations of analyte detecting members. This facilitates the assembly and integration of analyte detecting members 308 with cartridge 300. These analyte detecting members 308 may enable an integrated body fluid sampling system where the penetrating members 302 create a wound tract in a target tissue, which expresses body fluid that flows into the cartridge for analyte detection by at least one of the analyte detecting members 308. The substrate 322 may contain any number of analyte detecting members 308 suitable for detecting analytes in cartridge having a plurality of cavities 306. In one embodiment, many analyte detecting members 308 may be printed onto a single substrate 322 which is then adhered to the cartridge to facilitate manufacturing and simplify assembly. The analyte detecting members 308 may be electrochemical in nature. The analyte detecting members 308 may further contain enzymes, dyes, or other detectors which react when exposed to the desired analyte. Additionally, the analyte detecting members 308 may comprise of clear optical windows that allow light to pass into the body fluid for analyte analysis. The number, location, and type of analyte detecting member 308 may be varied as desired, based in part on the design of the cartridge, number of analytes to be measured, the need for analyte detecting member calibration, and the sensitivity of the analyte detecting members. If the cartridge 300 uses an analyte detecting member arrangement where the analyte detecting members are on a substrate attached to the bottom of the cartridge, there may be through holes (as shown in FIG. 76), wicking elements, capillary tube or other devices on the cartridge 300 to allow body fluid to flow from the cartridge

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to the analyte detecting members 308 for analysis. In other configurations, the analyte detecting members 308 may be printed, formed, or otherwise located directly in the cavities housing the penetrating members 302 or areas on the cartridge surface that receive blood after lancing.

Beginning on P. 16, Line 29 (DT)

[0079] The use of the seal layer 320 and substrate or analyte detecting member layer ~~822~~ 322 may facilitate the manufacture of these cartridges 10. For example, a single seal layer 320 may be adhered, attached, or otherwise coupled to the cartridge 300 as indicated by arrows 324 to seal many of the cavities 306 at one time. A sheet 322 of analyte detecting members may also be adhered, attached, or otherwise coupled to the cartridge 300 as indicated by arrows 325 to provide many analyte detecting members on the cartridge at one time. During manufacturing of one embodiment of the present invention, the cartridge 300 may be loaded with penetrating members 302, sealed with layer 320 and a temporary layer (not shown) on the bottom where substrate 322 would later go, to provide a sealed environment for the penetrating members. This assembly with the temporary bottom layer is then taken to be sterilized. After sterilization, the assembly is taken to a clean room (or it may already be in a clear room or equivalent environment) where the temporary bottom layer is removed and the substrate 322 with analyte detecting members is coupled to the cartridge as shown in FIG. 6. This process allows for the sterile assembly of the cartridge with the penetrating members 302 using processes and/or temperatures that may degrade the accuracy or functionality of the analyte detecting members on substrate 322. As a nonlimiting example, the entire cartridge 300 may then be placed in a further sealed container such as a pouch, bag, plastic molded container, etc . . to facilitate contact, improve ruggedness, and/or allow for easier handling.